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10/658,782	09/08/2003	Phillip Arcangel	PP-19199.002	7355

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EXAMINER

MCGAW, MICHAEL M

ART UNIT PAPER NUMBER

1648

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Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/658,782	<b>Applicant(s)</b> ARCANGEL ET AL.	
	<b>Examiner</b> Michael M. McGaw	<b>Art Unit</b> 1648	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 03 May 2004.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-32 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-32 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>5/3/04 and 9/8/03</u> . | 6) <input checked="" type="checkbox"/> Other: <u>Sequence sheets</u> .                  |

## DETAILED ACTION

### ***Claim Rejections - 35 USC § 112, ¶2***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 2, 3, 6 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Under subpart (a) of claim 1 applicant refers to “one or more ***isolated*** antigens from a ***first*** region of the HCV polyprotein.” (emphasis added) It is not clear what applicant means by referring to either an “isolated antigen” or a “first region.”

In what way is the antigen isolated? On page 18 of the specification applicant states “[b]y ‘isolated’ is meant, when referring to a polypeptide, that the indicated molecule is separate and discrete from the whole organism with which the molecule is found in nature or is present in the substantial absence of other biological macromolecules of the same type.” If there is more than one antigen then would this still be ‘isolated’ or does this definition not apply to antigens?

Furthermore, it says one *or more* isolated antigens. Does this system use multiple antigens? Or is the claim indicating that an antigen can contain one or more antigenic epitopes?

As for the region, it is “first” relative to what? Likewise, claim 2 refers to a first region.

It appears that the applicant has redefined the term "epitope" to encompass something substantially greater than that which would be included in the more common definition of the term. On page 13 of the specification the applicant defines "epitope" as follows:

The term "epitope" as used herein refers to a sequence of at least about 3 to 5, preferably about 5 to 10 or 15, and not more than about 1,000 amino acids (or any integer there between), which define a sequence that by itself or as part of a larger 25 sequence, binds to an antibody generated in response to such sequence. There is no critical upper limit to the length of the fragment, which may comprise nearly the full-length of the protein sequence, or even a fusion protein comprising two or more epitopes from the HCV polyprotein.

A more common definition is "the simplest form of an antigenic determinant, on a complex antigenic molecule, which can combine with antibody or T-cell receptor." (Stedman's Medical Dictionary, 27<sup>th</sup> Ed.) Another definition would be "A single antigenic determinant. Functionally it is the portion of an antigen which combines with the antibody paratope." (Immunology, Third Ed. (1993) Roitt, I.M. et al., Eds. Mosby\_Year Book Europe Ltd. Glossary definitions) Certainly under either definition an epitope is substantially shorter than 1,000 amino acids. It has been provided that "[w]here applicant acts as his or her own lexicographer to specifically define a term of a claim contrary to its ordinary meaning, the written description must clearly redefine the claim term and set forth the uncommon definition so as to put one reasonably skilled in the art on notice that the applicant intended to so redefine that claim term." *Process Control Corp. v. HydReclaim Corp.*, 190 F.3d 1350, 1357, 52 USPQ2d 1029, 1033 (Fed. Cir. 1999). While the term has been redefined, a question as to the adequacy of the notice of the change in definition is an issue with the examiner.

Claim 3 states “wherein the HCV antigens consist of one or more isolated HCV NS3/4a conformational epitopes...” It is not clear what the applicant means by this phrase. How, or in what context, is the epitope isolated? On page 18 of the specification applicant states “[b]y ‘isolated’ is meant, when referring to a polypeptide, that the indicated molecule is separate and discrete from the whole organism with which the molecule is found in nature or is present in the substantial absence of other biological macromolecules of the same type.” If this definition is extended to an epitope it would lead to the conclusion that the epitope has been removed from the environment of the epitopes surrounding it in the molecule. Yet, as becomes apparent, an “epitope” as defined by the specification can include natural sequences up to 1,000 residues in length. Surely such a long polypeptide would have other epitopes in the adjacent regions, thus not qualifying as “isolated”.

Claims 3-32 are rejected for using an incompatible combination of closed language in the independent claim followed by open claim language directed to the same term in dependent claims therefrom. As above, claim 3 states “wherein the HCV antigens **consist of** one or more isolated HCV NS3/4a conformational epitopes...” (emphasis added) Subsequent claims use incompatible claim language. For instance, claim 4 is directed to “[t]he method of claim 3, wherein said NS3/4a conformational epitope **comprises** an epitope from the NS3/4a protease region of the HCV polyprotein.” The closed claim language of “consist of” is incompatible with the broadening language effected by the open terminology “comprises”.

Claim 6 is unclear when it refers to “said NS3/4a conformational epitope comprises the amino acid sequence depicted in Figures 3A-3D (SEQ ID NO:2).” This corresponds to a sequence whose length is 686 amino acids. This is far greater than the length any one epitope within the region. In fact, a comparison with Figure 1 indicates that it is the entire NS3/4a region. The examiner is interpreting this as claiming a MEFA comprising SEQ ID NO:2.

Furthermore, it should be noted that it is not completely clear whether applicant is claiming the sequence in the figures 3A-3D or the sequence in SEQ ID NO: 2. Are they exactly the same sequence? Why doesn't applicant just claim the sequence as in SEQ ID NO:2? A similar question could be raised in reference to claims 15, 16, 22, 31 and 32.

In claim 1 part (c) it is specified that the “MEFA comprises at least one epitope from the same region of the HCV polyprotein as the one or more isolated antigens...” In subsequent independent claims it does not appear that the MEFA and the one or more isolated antigens must contain an epitope from the same region, though it does appear from figure 2, and also on an intuitive level since it is an antibody being “sandwiched” between the antigens, that the MEFA and the one or more isolated antigens must necessarily contain the same epitope. On the other hand, in the independent claims subsequent to claim 1 it does specify that the one or more isolated antigens must be conformational epitopes. Must the one or more isolated antigens and the MEFA contain epitopes from the same region? The point of this is that it would seem that *if* (1) the epitope of the one or more antigens must be conformational (as for instance

independent claim 3 indicates) and *if* (2) the MEFA and the one or more antigens must contain the same epitope, *then* the MEFA must also contain a conformational epitope. As one can never predict *a priori* whether an epitope in a chimera will be conformational, additional guidance is required in such a circumstance. This is particularly applicable to claims such as claims 9 and 25 where the examiner can find little guidance as to the particular operability of such a construct.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-5, 7-8, 10-14, 17-21, 23-24 and 26-30 rejected under 35 U.S.C. 103(a) as being unpatentable over Chien et al. (1999) in view of Seidel et al.

The claims are drawn to a method of detecting hepatitis C virus infection using a multiple epitope fusion antigen (MEFA) where the MEFA comprises at least one epitope in common with an antigen and either the antigen or the MEFA is used as the solid support. Claims subsequent to claim 1 require that the MEFA and the antigen to possess at least one epitope from the NS3/4a region or a specific region of the NS3/4a region. Claims 1-16 are directed to a system whereby it is the "one or more antigens" that are bound to the solid support and the MEFA is subsequently added; a version of a

double antigen bridge test. Claims 19-32 are directed to a system whereby it is the MEFA bound to the solid support and it is the one or more antigens that are subsequently added; also a double antigen bridge.

Chien et al. (1999) Journal of Clinical Microbiology, vol. 37, No. 5; p. 1393-97 teach a method of detecting hepatitis C virus infection in a biological sample using a MEFA containing all of the major immunogenic epitopes of HCV where the MEFA comprises at least one epitope in common with the antigen used in the solid support. (See abstract) As to the specificity of particular epitopes, Chien's MEFA-6 chimeric polypeptide included epitopes from throughout NS3/NS4a including both the helicase and protease regions as well as the c33c region of NS3 (spanning amino acids 1,192 to 1,457) and the 5-1-1 region of NS4a (spanning amino acids 1,689-1,735). See Figure 1 of Chien et al (1999) on page 1394 for the particulars of MEFA-6. Chien employed a system whereby the MEFA was coated on the plates, test sample containing anti-HCV antibody was added, and then conjugated antibody was added to detect the anti-HCV antibody bound to the MEFA. Thus, Chien et al did not employ a double antigen bridge test.

Seidel et al teach a double antigen bridge test using HCV antigens from the NS3 region in immunological tests (U.S. Pat. No. 6,306,579 B1). (See col. 4, lines 16-25). Seidel indicates that, when compared to other formats, a double antigen bridge results in both increased sensitivity (other immunoglobulin classes are recognized) and increased specificity (fewer unspecific reactions are seen).



One of ordinary skill in the art would have been motivated to combine the teachings of Chien with those of Seidel to create an immunological test for the detection of HCV-specific antibodies using a MEFA in a double antigen bridge format because Seidel et al indicates that the double antigen bridge format results in increased specificity and sensitivity. One of ordinary skill in the art would have expected to produce an immunological test for the detection of HCV-specific antibodies using MEFAs with enhanced sensitivity because Chien et al. teaches the efficacy of MEFAs in binding HCV-specific antibody while Seidel teaches the improved performance of the double antigen bridge format in the context of an immunological test for HCV-specific antibody to the NS3 region. Therefore the invention as a whole would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made.

Claims 1-5, 7-8, 10-14, 17-21, 23-24 and 26-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Valenzuela et al. in view of Seidel et al.

As outlined above, the claims are drawn to a method of detecting hepatitis C virus infection using a multiple epitope fusion antigen (MEFA) where the MEFA comprises at least one epitope in common with an antigen and either the antigen or the MEFA is used as the solid support.

Valenzuela et al. (US Pat. No. 6,428,792 B1) teach a method of detecting hepatitis C virus infection in a biological sample using a MEFA containing all of the major immunogenic epitopes of HCV where the MEFA comprises at least one epitope in common with the antigen used in the solid support (See abstract) Valenzuela's MEFA-3,

MEFA-5 and MEFA-6 chimeric polypeptides included epitopes from the NS3(protease)/NS4a(helicase) region (see fig. 1A-1C). Valenzuela employed a system whereby the MEFA was coated on the plates, test sample containing anti-HCV antibody was added, and then conjugated antibody was added to detect the anti-HCV antibody bound to the MEFA. Thus, Valenzuela et al did not employ a double antigen bridge test.

Seidel et al teach a double antigen bridge test using HCV antigens from the NS3 region in immunological tests (U.S. Pat. No. 6,306,579 B1). (See col. 4, lines 16-25). Seidel indicates that, when compared to other formats, a double antigen bridge results in both increased sensitivity (other immunoglobulin classes are recognized) and increased specificity (fewer unspecific reactions are seen).

One of ordinary skill in the art would have been motivated to combine the teachings of Valenzuela with those of Seidel to create an immunological test for the detection of HCV-specific antibodies using MEFA in a double antigen bridge format because Seidel et al indicates that the double antigen bridge format results in increased specificity and sensitivity. One of ordinary skill in the art would have expected to produce an immunological test for the detection of HCV-specific antibodies using MEFAs with enhanced sensitivity because Valenzuela et al. teaches the efficacy of MEFAs in binding HCV-specific antibody while Seidel teaches the improved performance of the double antigen bridge format in the context of an immunological test for HCV-specific antibody to the NS3 region. Therefore the invention as a whole would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made.

Claims 15, 16, 31 and 32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Valenzuela in view of Seidel as applied to claims 1-5, 7-8, 10-14, 17-21, 23-24 and 26-30 above, and further in view of Valenzuela et al (U.S. Pat. No. 6,428,792) or (in the alternative further in view of Chien et al. (1999)).

These claims are directed to a MEFA that comprises either SEQ ID NO: 4 (MEFA 12) or SEQ ID NO: 6 (MEFA 7.1). These SEQ ID's contain the epitopes as outlined in figures 5 and 7. These epitopes/antigenic regions are E1, E2, C33C, 5-1-1, C-100, NS5 and core.

Both Valenzuela and Chien have been discussed above. Importantly, both teach MEFA-6. Valenzuela also teaches MEFAs 3 and 5. These MEFAs contain the epitopes/antigenic regions are E1, E2, C33C, 5-1-1, C-100, NS5 and core. While the arrangement of the epitopes in the MEFAs is different, the epitopes found in the MEFAs are the same. Furthermore, Valenzuela teaches that the order of the MEFAs can be shuffled by showing the efficacy of the various MEFA constructs where the epitopes are rearranged.

One of ordinary skill in the art would have been motivated to include the epitopes/antigenic regions are E1, E2, C33C, 5-1-1, C-100, NS5 and core in a MEFA directed against the NS3/4a region of the HCV polypeptide because both Chien and Valenzuela showed the efficacy of these epitopes in a MEFA. One of ordinary skill in the art would have expected to produce a MEFA capable of detecting antibody specific to these antigenic epitopes/regions because Valenzuela teaches that these regions

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function in the context of a MEFA used in an immunological test even where their order has been rearranged. Therefore the invention as a whole would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made. While Valenzuela may not have explicitly directed one to the particular order found in the MEFAs of the present application, it is evident that the order of the MEFAs can be altered. In the absence of some unexpected properties or results associated with the order of the MEFA as found in the claims at issue, merely reshuffling the MEFA would be obvious.

Claims 6, 15, 16, 22, 31 and 32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chien et al (WO200196870-A2) in view of Seidel.

Chien et al (WO200196870-A2) discloses the identical amino acid sequences to that of the instant application. (See the included sequence listing sheets.) . In other aspects the reference is largely cumulative to that discussed above for Chien et al. (1999) or Valenzuela et al. Chien (WO200196870-A2) does not teach the double antigen bridge.

The applied reference has a common assignee with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the

invention "by another," or by an appropriate showing under 37 CFR 1.131. Seidel et al. teaches the double antigen bridge as discussed above.

One of ordinary skill in the art would have been motivated to combine the teachings of Chien (WO200196870-A2) with those of Seidel to create an immunological test for the detection of HCV-specific antibodies using MEFA in a double antigen bridge format because Seidel et al indicates that the double antigen bridge format results in increased specificity and sensitivity. One of ordinary skill in the art would have expected to produce an immunological test for the detection of HCV-specific antibodies using MEFAs with enhanced sensitivity because Chien et al. teaches the efficacy of MEFAs in binding HCV-specific antibody while Seidel teaches the improved performance of the double antigen bridge format in the context of an immunological test for HCV-specific antibody to the NS3 region. Therefore the invention as a whole would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made.

Claims 1-5, 7-8, 10-14, 17-21, 23-24 and 26-30 rejected under 35 U.S.C. 103(a) as being unpatentable over Chien et al. (1992) in view of Seidel et al.

The claims are drawn to a method of detecting hepatitis C virus infection using a multiple epitope fusion antigen (MEFA) where the MEFA comprises at least one epitope in common with an antigen and either the antigen or the MEFA is used as the solid support. Claims subsequent to claim 1 require that the MEFA and the antigen to possess at least one epitope from the NS3/4a region or a specific region of the NS3/4a region.

Chien et al. (1992) Proc. Nat. Acad. Sci., vol. 89; pp. 10011-10015 teach an immunodominant chimeric polyprotein, which would also constitute a MEFA, using regions from NS3, NS4 and C of HCV to be used in assays formats such as ELISAs. The epitopes in one of the chimeric polyproteins, designated c25, is shown in fig. 1 on page 10012. The c25 polyprotein contained epitopes from the the NS3(protease)/NS4a(helicase) region. Chien et al did not employ a double antigen bridge test.

Seidel et al teach a double antigen bridge test using HCV antigens from the NS3 region in immunological tests (U.S. Pat. No. 6,306,579 B1). (See col. 4, lines 16-25). Seidel indicates that, when compared to other formats, a double antigen bridge results in both increased sensitivity (other immunoglobulin classes are recognized) and increased specificity (fewer unspecific reactions are seen).

One of ordinary skill in the art would have been motivated to combine the teachings of Chien with those of Seidel to create an immunological test for the detection of HCV-specific antibodies using MEFA in a double antigen bridge format because Seidel et al indicates that the double antigen bridge format results in increased specificity and sensitivity. One of ordinary skill in the art would have expected to produce an immunological test for the detection of HCV-specific antibodies using MEFAs with enhanced sensitivity because Chien et al. teaches the efficacy of MEFAs in binding HCV-specific antibody while Seidel teaches the improved performance of the double antigen bridge format in the context of an immunological test for HCV-specific

antibody to the NS3 region. Therefore the invention as a whole would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made.

Claims 9 and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chien et al. (1992) in view of Seidel et al. as applied to claims 1-5, 7-8, 10-14, 17-21, 23-24 and 26-30 above, and further in view of Chien et al. (1992).

Claims 9 and 25 indicate that the MEFA comprises amino acids 1193-1657 of the HCV sequence. This is the portion of NS3 that corresponds to the helicase region.

Chien et al. (1992) is described more fully above. Importantly, Figure 1 of Chien et al. (1992) on page 10012 indicates that the C33C polypeptide which was part of Chien's C25 chimeric polypeptide is derived from the NS3 region. Also on page 10012 Chien indicates that "[t]he C33C polypeptide ... is derived from most of the NS3 region that appears to encode both a viral protease and a helicase." (See the last full line of col. 1) It is not clear from the disclosure whether Chien included the entire helicase region in his MEFA, as currently claimed by applicant, but the statement certainly strongly suggests its inclusion.

One of ordinary skill in the art would have been motivated to include the helicase peptide in a MEFA containing epitopes directed against the NS3/4a region of the HCV polypeptide because Chien et al. showed the efficacy of helicase epitopes and indicated the importance of the inclusion of antigenic determinants from the helicase region. One of ordinary skill in the art would have expected to produce a MEFA capable of detecting antibody specific to the helicase region because Chien et al. teaches the efficacy of

such an epitope in a MEFA. Therefore the invention as a whole would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made.

### ***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-30 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-20 of U.S. Patent No. 6,428,792 B1. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the instant application are broadly directed at methods of using MEFAs, while the claims of the patent are directed to broad product claims for MEFAs while disclosing the utility of such MEFAs in exactly the immunoassay format claimed in the methods of the present application. Furthermore, the MEFA claims of the prior patent read on the MEFAs disclosed in the methods of the present application.




***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael M. McGaw whose telephone number is (571) 272-2902. The examiner can normally be reached on Monday through Friday from 8 A.M. to 5 P.M..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on (571) 272-0902. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Tuesday, August 03, 2004

  
**MARY E. MOSHER**  
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